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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,503	HABER ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 1-22 are rendered uncertain by the phrase "A cholesterol-reducing agent comprising at least one dietary fiber selected from the group consisting of carob fruit flesh, a product isolated from carob fruit flesh or levan and at least one cholesterol-reducing active ingredient, except for a combination of a) a dietary fiber and b) an aryl-substituted propanolamine derivative or 1,4-benzothiepine 1,1-dioxide derivative". In claim 1, line 2, in claim 3, line 2 in claim 7, line 2 and in claim 8, line 2, it is unclear as to what Applicant means by the term "carob fruit flesh" is. In the instant case, "carob fruit flesh" is taken to mean "carob pod". In claim 1, lines 2 and 3, in claim 3, line 2, in claim 7, line 3 and in claim 8, line 3, it is unclear as to what Applicant means by the phrase "a product isolated from carob fruit flesh". Applicant could be referring to the seeds of carob pods or to compounds extracted from carob pods. In claim 1, lines 3-5 and claim 7, lines 3-5 the phrase "except for a combination of a) a dietary fiber and b) an aryl-substituted propanolamine derivative or 1,4-benzothiepine 1,1-dioxide derivative" is vague and should be

omitted from the claim as it does not clearly define what Applicant is claiming. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claims 1-22 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethnopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical as noted in this application. The common name or traditional/ethnopharmacological name may have several different Latin names referring to various genus-species of the plant and it is unclear as to which genus and species Applicant is referring. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Applicant may overcome the rejection by placing the genus-species name of "carob" in parentheses after the term "carob".

The metes and bounds of Claim 2 are rendered uncertain by the phrase "of from 1 to 50 g" because the simultaneous recitation of the terms "of" and "from" makes the claim language inconsistent. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claims 2 and 9 recite the limitation "the dietary fibers" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the active ingredient" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The metes and bounds of Claim 7 are rendered uncertain by the phrase "wherein said dietary fiber and said cholesterol-reducing active ingredient are present in separate administration forms". It is unclear as to what Applicant means by "separate administration forms", especially since Applicant is claiming a composition comprising of a dietary fiber and a cholesterol-reducing active ingredient. "Separate administration forms" could refer to different modes of administration (ie. fiber could be administered as a powder and cholesterol-reducing active ingredient could be administered as a liquid) or "separate administration forms" could refer to different physical forms of each ingredient prior to mixing them together to provide a food, a drug or any other composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Burgin (A).

Burgin teaches a soluble fiber dietary supplement composition for reducing cholesterol (which reads on a cholesterol-reducing agent, a cholesterol-reducing combination and a food ingredient) comprising of fiber (See column 1, lines 7-10), which has been shown to be an effective hypocholesterolemic agent (See column 3, lines 37-39), in the form of guar gum (which reads on guar) (See column 1, lines 12-15), locust bean gum (which is a product isolated from carob fruit flesh) (See column 1, lines 62-63, 66-67 and continued into column 2. lines 1-3), psyllium (See column 6, lines 2527) and pectin, which can be obtained from grapefruit (See column 6, lines 25-29). Burgin further teaches that grapefruit pectin is known to lower cholesterol in humans (See column 3, lines 42-46) and reads on a cholesterol-lowering agent, cholesterol-reducing plant extract and cholesterol-reducing food ingredient. Burgin further teaches that typically, the fiber composition contains 5 grams of fiber (See column 7, Example 2), which reads on a daily dose from 1 to 50 g. Burgin does not expressly teach that the composition is provided in a daily dose, however the composition comprising of fiber and a cholesterol reducing agent, which is administered in conjunction with cholesterol lowering medication (which is administered daily), as taught by Burgin, is one and the same as that claimed by applicant.

Therefore, the reference anticipates the claimed subject matter.

Claims 1, 5 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Seneci (B), as evidenced by Zunft et al. (Cited in IDS).

Seneci teaches a composition comprising of soluble fibre (please note that fibre is synonymous with fiber) from carob or carob seeds and insoluble fibre from carob or carob seeds (See page 1, paragraph 0009), please note that insoluble dietary fiber from carob pulp, which is obtained from carob pod, is found to reduce cholesterol (See Zunft). Seneci teaches a method of mixing insoluble and soluble fibers together (See page 1, paragraph 0007) to provide the instantly claimed invention.

Therefore, the reference anticipates the claimed subject matter.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cavadini et al. (C), as evidenced by Anthony et al. (U).

Cavadini teaches a pet food (See abstract), which reads on feedstuff (please note that feedstuff is synonymous with animal feed) and animal feed, comprising of fiber from carob bean gum (See column 3, line 67 continued onto column 4, lines 1-3), which reads on a product isolated from carob fruit flesh, and soy protein concentrate (See column 3, lines 47-51). Please note that soy protein concentrate contains isoflavones, which are known to reduce atherosclerosis and lower lipid concentrations (See Anthony, especially the Abstract on page 1350s), which reads on cholesterol-reducing agent and cholesterol-reducing active ingredient.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 13-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (D), in view of Burgin (A).

Bell teaches a pharmaceutical composition (See column 2, lines 21-24) to manage blood lipids, such as total cholesterol and LDL cholesterol (See column 2, lines 54-61), comprising of psyllium husk fiber, which is known to lower cholesterol and treat hypercholesterolemia (See column 5, lines 19-34). Bell further teaches carob as a flavoring agent (See page 35, lines 35-39). Bell further teaches that the ingredients can be separately assembled: some

components can be assembled into a tablet or capsule and the remaining ingredients can be assembled into a power to add to a beverage. Bell further teaches that the two assembled forms can be packaged together or separately and they can be administered together or separately (See column 12, lines 47-56).

The teachings of Burgin are set forth above and applied as before.

The teachings of Bell and Burgin are set forth above. Bell does not expressly teach a drug comprising of carob fiber and a cholesterol-reducing active ingredient. However, it would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to combine carob fiber and psyllium fiber, which is a cholesterol-reducing agent, as taught by Burgin, to make a drug to reduce cholesterol and treat hypercholesterolemia, since at the time the invention was made, the combination of psyllium fiber and carob to make a drug to manage blood lipids was well known in the art, as clearly taught by Bell, as were the beneficial effects of psyllium fiber and carob fiber on treating cholesterol and for treatment of hypercholesterolemia, as clearly taught by both Bell and Burgin.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crocketti*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy L. Clark
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Amy L. Clark
February 13, 2006

Michele C. Flood.
MICHELE FLOOD
PRIMARY EXAMINER